

MANUFACTURING EXTENSION PARTNERSHIP

Success Stories from the Field

Cutting Edge Instruments

Vermont Manufacturing Extension Center

Cutting Edge Instruments Achieves ISO 13485:2003 Certification

Client Profile:

Cutting Edge Instruments (CEI), founded in 2002, manufactures carbide dental burs used by dentists. The company is located in Bridgewater Corners, Vermont, and employs 17 people.

Situation:

CEI recognized that achieving ISO 13485:2003 certification would allow them to expand their sales and marketing efforts in Europe and Canada and increase U.S. military and government sales. ISO 13485:2003 is a requirement for applying for the Canadian CMDCAS and the European CE mark certifications. CEI engaged the Vermont Manufacturing Extension Center (VMEC), a NIST MEP network affiliate, in October of 2004 to assist them in preparing for these certifications.

Solution:

VMEC is a part of the New England Manufacturing Supply Chain Consortium (NEMSC), a partnership that seeks to align manufacturing system capabilities to opportunities to pursue defense supply chain solicitations. NEMSC supported the project from the outset. The first step was to perform a gap analysis of the existing ISO 9002-compliant quality system. VMEC tapped the vast expertise of Joseph Azary of Azary Technologies LLC. Azary Technologies specializes in helping companies prepare their quality systems to meet the requirements of medical device and FDA certification. Mr. Azary used the results of a gap analysis to work with VMEC and CEI personnel to incorporate the more stringent requirements of ISO 13485:2003 into their quality system. CEI also brought in Edgar Bothe, a quality consultant, to help supplement their available internal resources. The combined effort allowed the company to modify their system in just over two months. This included review of all documentation, modifying procedures where necessary, training personnel, and verifying compliance to the new system so that "living the system" continues to yield the largest business benefit possible to the company.

Results:

- * Achieved ISO 13485:2003 certification in January 2005.
- * Applied for CMDCAS and CE mark certification.
- * Projected new sales of \$1 million.
- * Reduced work in process for cost savings of \$4,000.
- * Improved design procedures for cost savings of \$4,000.
- * Invested \$18,200 in software and workforce practices.
- * Produced direct labor cost savings of \$33,000.
- * Created two new positions in production areas.

Testimonial:

www.mep.nist.gov



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"As a small Vermont manufacturer competing on a global basis, we need to capitalize on every advantage and resource available to us in order to accomplish our goals. VMEC has become a strategic and beneficial partner in a very short time. With the direct assistance of Brenda Kelly and the team of consultants we partnered with, we have recently accomplished our new ISO 13485:2003 certification. Due to inadequate preparation and training by a previous "expert consultant company," our company was behind the 8-ball in attaining our required certifications to allow us to participate in securing contracts in several countries. Brenda and her team embraced our situation and assisted us in attaining our certification in just over two months. This accelerated plan required total commitment and cooperation from all involved. The VMEC team worked well with our employees in assisting and educating as needed. The questions asked, suggestions given and "what if's" proposed were very insightful, useful and in some cases immediately applied. I certainly appreciate having assistance and expertise such as we have experienced available to us through VMEC."

Scott Andrews, Vice President of Sales